UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris

SCHERING-PLOUGH CORPORATION'S AND WARRICK PHARMACEUTICAL CORPORATION'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS

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Defendants Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals Corporation ("Warrick") respectfully submit this opposition to Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants ("Plaintiffs' Motion").

INTRODUCTION

As explained in Defendants' Joint Memorandum, Plaintiffs seek summary judgment on issues as to which they bear the ultimate burden of persuasion at trial, which means that their burden in support of summary judgment is extraordinarily high; indeed it is insurmountable. In addition to the propositions they must prove as to all of the Defendants and all of the accused drugs, with respect to generic and multi-source drugs manufactured by Schering and Warrick, which were reimbursed by Medicare based on a median AWP, they must also proffer evidence sufficient if unrebutted to entitle them to a directed verdict that a change in the AWP of these specific generic and multi-source products would have affected the median AWP for all generic and multi-source products of the kind, and thus would have changed the reimbursement rate for all generic and multi-source products of the kind.

Far from attempting to meet this burden, Plaintiffs simply ignore critical facts. At the beginning of their brief, Plaintiffs concede that multi-source drugs, such as Warrick's generic albuterol and Schering's multi-source albuterol (named Proventil) – which together account for 93% of the damages claimed by the Medicare classes from Warrick and Schering – are reimbursed based on the median AWP for all forms of the product, including forms manufactured by competitors. (Pls.' Mem. Supp. Mot. Partial Summ. J. Against All Track 1 Defs. at 4.) ("Pls.' Mem.") But Plaintiffs then make their entire argument for summary judgment against Warrick and Schering as though median-based reimbursement did not exist. Schering and Warrick had no incentive to affect the median, virtually no ability to affect it, and in fact did

nothing to affect it. Given these truly indisputable facts regarding the vast bulk of the accused drugs, it is entirely illogical, and indeed pure fantasy, to suggest that the evidence compels the conclusion that Schering and Warrick "purposefully manipulated and marketed spreads," including those they had no incentive or ability or activity to affect. Indeed, Schering and Warrick have demonstrated in their motion for summary judgment that they have been responsible participants in a pricing and reimbursement system that they did not create, and that they have achieved success with their products (and resulting market share) as a result of competition, and not manipulation. These are but a few of the many reasons that Plaintiffs' Motion must fail.[1]

ARGUMENT

I. PLAINTIFFS UNJUSTIFIABLY CONFLATE MANUFACTURER SALE PRICE WITH PHYSICIAN ACQUISITION COST

A. Plaintiffs Have Changed Their Theory of the Case

As a threshold matter, Plaintiffs have, in their summary judgment papers, presented shifting theories of their case. Plaintiffs have spent several years arguing that AWPs should have been more closely related than they were to the actual costs paid by the physicians and pharmacies that administer or dispense the drugs. Their theory has been that the Defendants inflated AWPs to create and/or increase "spreads" between AWPs and providers' costs to give providers an incentive to purchase the drugs with the most inflated AWPs. (Fourth Amended Master Consolidated Complaint (Mar. 1, 2006) (Docket Nos. 2171-2176) ("FAMCC") ¶ 151.) Plaintiffs now argue that AWPs should have been more closely related to the *manufacturer's* price, which is *not* the provider's cost because a manufacturer's price necessarily excludes the mark-ups of the wholesalers or other intermediaries who purchase the drugs from the

[1] Other reasons why Plaintiffs' Motion should be rejected are set forth in the Joint Opposition, which Schering and Warrick adopt.

manufacturers and re-sell them to the providers. This sleight-of-hand is significant because Plaintiffs do not and cannot quantify the wholesaler mark-ups, *i.e.*, they do not have evidence of providers' costs. Indeed, Plaintiffs admit this lack of evidence: counsel for Plaintiffs told the Court that "[provider] acquisition cost is apparently what doctors ultimately pay to acquire the drug. We don't know what that is." (Tr. of Hr'g before Magistrate Judge Bowler (Nov. 9, 2005) at 14, attached as Ex. A.[2])

Plaintiffs, through their entirely inappropriate reliance on HHS-OIG Guidelines, now argue that AWP should be Average *Manufacturers'* Price (AMP) and may be lower (approaching Best Price). Plaintiffs quote from statements made by Thomas Scully for the proposition that "AWP is intended to represent the average price at which *wholesalers sell* drugs to their customers," and then, inconsistently, they rely on HHS-OIG "guidance" to further "define" AWP in terms of prices at which *wholesalers buy* drugs from manufacturers:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues).

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23,733-34 (May 5, 2003), attached as Ex. C to Decl. of Steve W. Berman in Supp. of Plaintiffs' Mem. for Partial Summ. J. Against All Track 1 Defs ("Berman Decl."). The section of the OIG guidance from which this quote is taken is discussing the calculation of Average *Manufacturer's* Price (AMP) and related Best Price. In making these arguments about *manufacturer's* price,

[2] All citations to "Ex. __" will refer to exhibits to the Declaration of Eric P. Christofferson Transmitting Documents Relied upon in Schering's and Warrick's Memorandum in Opposition to Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants.

Plaintiffs apparently abandon their argument that AWP is defined as a provider's acquisition cost or even that AWP has an expected relationship to providers' acquisition costs.

The shifting sands of Plaintiffs' arguments make it difficult to respond without getting tangled in Plaintiffs' illogic. For example:

- As Plaintiffs are fully aware, there are many public and private reimbursement formulae that are based on a percentage discount off of AWP, and it is a precondition of them all that AWP is a benchmark that does not vary with the formula. By suggesting that AWPs were statutorily defined as prices less than the prices paid by providers, Plaintiffs suggest that providers were expected to take a loss each time they prescribed or dispensed an accused drug.

- Notwithstanding the fact that they are no longer making any effort to define AWP as a price paid by providers, Plaintiffs argue that they are entitled to judgment as a matter of law because "Defendants perpetuated publication of inflated AWPs while knowing full well that those same AWPs constitute the Medicare Part B reimbursement benchmark, *manipulated spreads between AWP and actual costs*, and took concrete steps to market those spreads to providers." (Pls.' Mem. at 121.) Plaintiffs' legal argument for summary judgment is simply divorced from the record they submit in support of that argument.

Plaintiffs seek to obscure the inconsistencies in their arguments by filing a 125-page brief in which they never once say precisely what they mean while, at the same time, repeatedly seeking to support their arguments regarding the "definition" of AWP by relying on citations and quotations addressed to other issues entirely. In so doing, Plaintiffs (a) seek to present irrelevant material to this Court as persuasive authority on the "definition" of AWP, (b) enable themselves significantly to inflate the "spreads" they present by reducing the base upon which they calculate those spreads, and (c) significantly inflate the damages they seek. For example, with regard to Schering and Warrick, Plaintiffs argue that the "favorable spreads" are created by "AWP-acquisition price differentials" – *i.e.*, the wrong alleged in the complaint – *and* "off-invoice inducements such as discounts, rebates, price-protected orders, free goods, grants, stock/inventory adjustment, and bundling of products with steeply discounted drugs" – which

relate to the prices at which the manufacturer sells and serve to inflate spreads and damages. (Pls.' Mem. at 113-15.)

B. Plaintiffs' New Theory Is Untenable

Plaintiffs assert that as a matter of statutory and regulatory interpretation, AWP is supposed to be "reasonably related" to "actual costs in the marketplace," that is, providers' acquisition cost, or, in Dr. Hartman's terminology, Actual (or Average) Acquisition Cost (AAC). (Pls.' Mem. at 42.) As discussed above, Plaintiffs have provided *no evidence whatsoever* about what constitutes the "actual costs in the marketplace" – AACs. At the same time, Plaintiffs have asserted liability and measured damages based on comparisons of AWP with a manufacturer's Average Sales Price (ASP). (Decl. of Raymond S. Hartman in Supp. of Pls.' Claims of Liability and Damages (Dec. 15, 2005) ("Hartman Decl.") ¶ 19, attached as Ex. B; Supp. Decl. of Raymond S. Hartman in Supp. of Pls.' Claims of Liability and Calculation of Damages: Addendum (Feb. 3, 2006) ¶ 2(b), attached as Ex. C.) Now they make recourse to something less than Average Manufacturer's Price, AMP, which is different from both AAC and ASP. All three measures of cost – AAC, AMP, and ASP – are different from one another, and Plaintiffs never explain how AWPs were historically supposed to "reflect" all of them.

Plaintiffs present no evidence or argument for the existence of a relationship among ASP, AMP and AAC. This is a *non sequitur* that undermines Plaintiffs' Motion, if not their entire case. The spreads – mega and otherwise – to which Plaintiffs continually refer are differences between AWP and *ASP*, whereas Plaintiffs say that the law as they interpret it requires proximity between AWP and "actual cost in the marketplace," which is *AAC*, and they argue for their statutory interpretation of AWP with reliance on HHS-OIG Guidelines discussing *AMP*, which definitely is not provider cost. Yet they never connect ASP or AMP with AAC, either logically or with evidence, to develop spreads of the kind that they say the law regards as important,

between AWP and AAC. Notably, Dr. Hartman's "expectations" are measurements of AWP-ASP, whereas the law measures proximity in terms of AWP-AAC, according to Plaintiffs. Thus, Dr. Hartman's "expectations" are legally irrelevant to Plaintiffs' theory.

Indeed, the HHS-OIG Guidelines on which the Plaintiffs so heavily and improperly rely in fact refute two of the Plaintiffs' major theses:

- The Guidelines are premised on the proposition that the existence of spreads *per se* is necessary and appropriate, without regard specifically to size, arguing instead that they are illegal only if they are purposefully manipulated and marketed. 68 Fed. Reg. 23,731, 23,737 (May 5, 2003), attached to Ex. C to Berman Decl.
- They define "spread" for the purpose of assessing manipulation and marketing as the difference between provider acquisition cost and provider reimbursement and not, as the Plaintiffs do, as the difference between AMP (or less) and provider reimbursement; specifically, the Guidelines define "spread" as "the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer." *Id.* at 23,736.

Despite Plaintiffs' shifting arguments, provider acquisition cost is central to the case they plead in all of their complaints and to their theory of Defendants' alleged wrongdoing, as it is to the conduct that the HHS-OIG argues against. Without that information, which they disclaim, they have no case, and they certainly have no argument for summary judgment.

II. PLAINTIFFS CANNOT ESTABLISH THAT SCHERING OR WARRICK MANIPULATED OR MARKETED SPEADS

As to the alleged manipulation and marketing of the spread, Plaintiffs have proffered a small number of documents, most of which do not relate to the accused drugs, and none of which

even suggests, let alone establishes, the propositions on which Plaintiffs bear the burden of proof. Moreover, Plaintiffs have misrepresented the record sources on which they do rely.

A. The General Marketing Evidence Cited by Plaintiffs Does Not Support the Propositions for Which It Is Proffered

Perhaps the most egregious example of misrepresentation is Plaintiffs' description of deposition testimony in other litigation of Louis Manfredi, a business development manager for Warrick.[3] (Pls.' Mem. at 112.) Plaintiffs quote Mr. Manfredi's response to a question asking for his understanding of the term "marketing the spread." Their presentation of this testimony is supposed to convey the impression that Mr. Manfredi is describing his own conduct and the conduct of others at Warrick when, in fact, Mr. Manfredi's responses to the next few questions show quite clearly that neither he nor anyone else at Warrick to his knowledge engaged in any such conduct:

> Q. Do you know if -- are you aware if any manufacturers use that spread to market for their products?
> MR. McDONALD: I object to the form.
> A. *I am not aware of that*.
> Q. In your experience in marketing generic pharmaceuticals and branded pharmaceuticals, do you ever use the spread to market pharmaceuticals?
> A. *No*. You use the direct price.

(Manfredi Dep. Tr. (Jul. 11, 2005) at 89-91, attached as Ex. D.) (emphasis added) Indeed, Mr. Manfredi expressly denied that he ever discussed reimbursement with any customer:

> Q. While you were at Warrick, did you ever discuss reimbursement with any Warrick customer?
> A. No.
> Q. While you were at Warrick, did you ever

[3] Tellingly, Plaintiffs nowhere attach a transcript of this deposition, even though they label it "SP Ex. 15." (*See* SP Ex. 15 (telefax from Harvey J. Weintraub), attached to Decl. of Steve W. Berman in Supp. of Plaintiffs' Mem. for Partial Summ. J. against All Track 1 Defs ("Berman Decl.").) In the portions of their brief relevant to Schering and Warrick, Plaintiffs also cite, but fail to attach, at least two other exhibits. (*See* Pls.' Mem. at 113 n.33 and 114 n.41.)

> discuss with any Warrick customer the difference between AWP and any reimbursement that customer may receive?
> A. No.
> Q. Previously you discussed the term "Marketing the Spread" with Ms. Solen. Do you recall that?
> A. Yes.
> Q. While you were at work did you ever market the spread to any Warrick customer?
> A. No.

(*Id.* at 103-04.) Thus, by the plain terms of the very "evidence" Plaintiffs would have this Court consider, Schering and Warrick did not "market the spread."

In addition, Plaintiffs also suggest that an email from Brian Longstreet, which Plaintiffs gratuitously label the "Longstreet Confession," is evidence of Schering's AWP "scheme." (Pls.' Mem. at 110.)[4] That suggestion is more than misguided. First, this email concerns a drug, Rebetol, that is not at issue in this case. Second, there is no evidence that any action was taken as a result of this email; indeed, Longstreet's concluded not to change any price or take any action and simply to "keep" the AWP where it was. (*Id.* at 111.) Thus, the email provides no evidence of any specific *act* of AWP manipulation. Third, Longstreet has testified that his purpose in writing the email was simply to describe "the reimbursement process as it relates to managed care organizations and potentially pharmacies." (Longstreet Dep. Tr. (Aug. 11, 2005) at 85, attached as Ex. E.) This email certainly fails to constitute evidence of a company-wide "scheme" to inflate and manipulate AWPs with respect to all drugs at issue over the entire class period.

[4] This is one of many instances in which Plaintiffs substitute hyperbole for evidence. For example, they dub a "concession" a letter to a government agency that underlines what has always been understood by the government and what has always been Warrick and Schering's position in this litigation: AWP is not an average of wholesale prices. (Pls.' Mem. at 119.) They construe an e-mail discussing a request from a hospital – from which no conduct is shown, much less any violation of law – as a "blatant example of misuse of offering grants for illegal incentives." (Pls.' Mem. at 114 n.39.)

B. Evidence Relating To Specific Drugs Does Not Show Any Wrongdoing

Plaintiffs present a small number of documents relating to three of the drugs at issue, but none of them shows any conduct that could be characterized as "manipulating and marketing the spread."

1. Integrilin

Plaintiffs present a handful of documents relating to Integrilin – a drug used in conjunction with angioplasties and to treat people who have just suffered a heart attack – but Plaintiffs' arguments are conclusory and nothing more than unwarranted inferences that no jury would be permitted to make. First, the Court should note that Plaintiffs' own liability expert did not find any liability as to Integrilin. (Hartman Decl. ¶ 61.) Moreover, as Plaintiffs concede, Integrilin is exclusively administered in hospitals and, thus, not appropriately marketed to physicians for outpatient treatment. In 2000, HCFA instituted the OPPS program in which Integrilin *might* be administered to emergency-room patients covered by Part B; but this rarely happens because someone who undergoes angioplasty or who has suffered a heart attack almost without exception needs a hospital stay, which is why Plaintiffs cannot find any damages with respect to Integrilin. The documents cited by Plaintiffs reveal the confusion among hospital providers that resulted from the establishment of the OPPS program, and they demonstrate Schering's efforts to explain the reimbursement requirements of that program to those providers.[5]

2. Intron and Temodar

With respect to Plaintiffs' purported "evidence" relating to Temodar and Intron, Plaintiffs' assertions are entirely misleading and border on the outrageous. Temodar is an oral

[5] Plaintiffs simply misrepresent some of the other documents. For example, Plaintiffs say that Schering sales representatives were given "outlines on the integrilin reimbursement spread advantage," but there are no such outlines or references to outlines in the cited exhibit. (Pls.' Mem. at 115, n.43.)

drug used to treat brain cancer. Plaintiffs state that, with respect to Temodar, "sales representatives confirmed that it was there [sic] standard practice to make reimbursement information a part of their sales pitch to customers." (Pls.' Mem. at 116.) The "reimbursement information" they provided, however, was not spread information, as Plaintiffs insidiously suggest. Rather, the Schering sales representatives explained repeatedly that discussions about reimbursement with physicians were rare and were primarily limited to answering questions about the mechanics of the Medicare reimbursement process posed by physicians who had not previously participated in the Medicare program. (Schering's and Warrick's 56.1 Stmt. ¶ 62.) In fact, the same sales representatives Plaintiffs sloppily cite[6] for this "standard practice" of using "reimbursement information" in conversations with customers are the same sales representatives who testified that they did not market the spread. (*See id.* ¶ 58 (collecting testimony of, *inter alia*, Gary Bishop, James Butler, and Mark D. Flynn).) In fact, not one sales representative testified to marketing the spread.

As to Intron A, the sole document that Plaintiffs label as evidence of marketing the spread is no such thing. The document compares the cost of administering Intron to treat bladder cancer with the cost of the only other available treatment: a $30,000 surgery. The document has nothing to do with marketing spreads on drugs, or even comparing spreads between competitors' drugs. Rather, it plainly shows an effort to convince doctors to use drug treatment in lieu of surgery, as witnesses have uniformly testified. (*See, e.g.*, Bishop Dep. (Jul. 17, 2005) at 89-91, attached as Ex. F.) Plaintiffs' description of the document is therefore entirely misleading.

[6] In footnote 50, Plaintiffs cite "SP Ex. 37," which they purport to be "SPW drug representatives' depositions." SP Ex. 37, however, does not include any depositions; it is a chart labeled "CVS Proposal." (*See* SP Ex. 37, attached to Berman Decl.) It appears that Plaintiffs meant to cite SP Ex. 34, which includes depositions of three Schering (not Warrick) sales representatives: Gary Bishop, James Butler, and Mark D. Flynn. (*See* SP Ex. 34, attached to Berman Decl.) Plaintiffs make similar errors in citations to exhibits included in footnotes 34 , 41, 44, 47, 48, 50, 54, and 56.

The remainder of the "evidence" that Plaintiffs proffer against Schering and Warrick amounts to nothing more than documents demonstrating that Schering and Warrick – like every company in America is supposed to do – competed on price. Indeed, Plaintiffs' own experts agree that discounting is a legitimate and lawful response to competition. (*See* Rosenthal Dep. Tr. (Feb. 22, 2006) at 212-13, 322-23, attached as Ex. G; Hartman Dep. Tr. (Mar. 1, 2006) at 1193, attached as Ex. H.) As explained in Schering's and Warrick's Memorandum Supporting Schering's and Warrick's Motion for Summary Judgment as to Class 2 Claims, price competition alone cannot form the basis of liability under Chapter 93A. *See, e.g.*, *Tagliente v. Himmer*, 949 F.2d 1, 7 (1st Cir. 1991); *see also Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Schering and Warrick have already explained why merely distributing price notifications cannot support liability. (Mem. Supp. Schering and Warrick Mot. Summ. J. at 17-19.) Plaintiffs have not presented any evidence that Schering or Warrick changed their AWPs in order to gain market share, as has been alleged. Nor have Plaintiffs presented any evidence that Schering or Warrick marketed the spread. For these reasons, Plaintiffs' Motion must fail.

III. SCHERING AND WARRICK HAVE PRESENTED AMPLE EVIDENCE DEMONSTRATING THAT PLAINTIFFS' CLAIMS FAIL

Not only have Plaintiffs failed to proffer sufficient evidence to meet their exacting burden at summary judgment, Schering and Warrick have presented ample evidence in their own Motion demonstrating that Plaintiffs' claims fail as a matter of law.

As explained in Schering's and Warrick's Motion, Plaintiffs' allegations concerning generic and multi-source products – which constitute more than 93% of the alleged damages against Schering and Warrick – vanish when viewed in light of median-based reimbursement under Medicare Part B. Even viewed most favorably within the context of Plaintiffs' allegations,

manufacturers simply have no incentive to manipulate a median-based reimbursement rate because a change in the rate would change the rate for all manufacturers, thus providing no competitive advantage. The mathematics of changing a median unilaterally are equally daunting.

Besides, Schering and Warrick have demonstrated that they have never manipulated the spread. In fact, Warrick did not change its AWPs in response to competition, or for any other reason, since 1995. Without an *act* of manipulation, which Plaintiffs cannot show, their claims fail. *See Tagliente*, 949 F.2d at 7 (awarding summary judgment to the defendant where "the record show[ed] . . . that the defendant committed no acts so misleading or deceptive to warrant recovery for [the plaintiff] under chapter 93A"); *Mulvihill v. Top-Flite Golf Co.,* 335 F.3d 15, 19 (1st Cir. 2003) (without specific acts, allegations and inferences alone will not "deflect the swing of the summary judgment scythe"). Similarly, because there is no evidence that Schering or Warrick did anything that had the effect of inflating the median, Plaintiffs cannot show that Warrick or Schering could possibly have caused any harm to Plaintiffs. *See, e.g., Markarian v. Connecticut Mut. Life Ins. Co.*, 202 F.R.D. 60, 68 (D. Mass. 2001) (a plaintiff "must prove 'but for' causation and proximate causation" to recover under Chapter 93A); *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 16 (1st Cir. 2001) ("causation remains a necessary element of a successful 93A claim").

Moreover, as explained in Schering's and Warrick's Motion, Plaintiffs' repeated assertions that Warrick and Schering intentionally manipulated AWPs to increase market share and gain a competitive advantage are belied by the facts. Warrick maintained relatively low AWPs for its albuterol products when compared with its competitors, but often enjoyed a large share of the market. (Mem. Supp. Schering and Warrick Mot. Summ. J. at 14.) Moreover, when Warrick's market share began declining, it did not adjust its AWPs. (*Id.*)

CONCLUSION

The foregoing are but a few of the reasons why Plaintiffs' Motion should be denied. Plaintiffs bear a particularly high burden of persuasion at trial; their burden of prevailing at summary judgment is even higher, and Plaintiffs have not nearly carried it. Thus, Schering and Warrick respectfully request that Plaintiffs' Motion be DENIED.

Schering-Plough Corporation and
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Dated: April 7, 2006

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson_____
Eric P. Christofferson